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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,266	04/15/2004	Wolfgang Beilfuss	Serie 6293	8115

7590 03/17/2008

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1797	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,266	BEILFUSS ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-28,34-63 and 66-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-28, 34-63, 66-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 January 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 67 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 67 sets forth a method of using a composition containing 1-(2-ethyl-hexyl) glycerol ether and an aromatic alcohol, wherein the composition is not capable of disinfecting an article absent thermochemical disinfection. The instant specification fails to disclose a single example showing the effectiveness of the claimed composition at both room and elevated temperatures. Example 1 shows only the effectiveness of phenoxyethanol (an aromatic alcohol) at room and elevated temperatures. Example 2 demonstrates that SC50 (a glycerol ether) has some antimicrobial effectiveness at room temperature, especially against mycobacteria. At the

very least, this particular example would teach one that the combination of SC50 with the aromatic alcohol would be capable of achieving some level of disinfection at room temperature.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 19-28, 34-36, 42-63, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saud et al. (US 2004/0001797) in view of Tu et al. (WO 92/09309).

With respect to claims 19-23, 25-27, 33-36, 42, 44, 46, 48-50, 57, 58, 62, 63, and 66, Saud et al. teaches a method of disinfecting a hard surface employing a composition containing 1-(2-ethylhexyl)glycerol ether in an amount of 0.1-10% of the total composition. See claim 19, paragraphs [0034], [0050], Table 1 – Ex.3. The composition contains additional agents such as citric acid (a carboxylic acid) in an amount of 1.5%, sodium hydroxide in an amount of 3%, and water. Additionally, the composition contains a salt, sodium glyceryl sulfonate. The pH is 3.0. See paragraph [0082]. The composition is packaged to be dispensed as a spray (i.e. atomized) ([0054]) or can be wiped on the surface ([0086]). Saud et al. further discloses that the hard surface cleaner is suitable for kitchen and bathroom surfaces (thermostable surfaces). The composition is allowed to contact the surface for "at least 30 seconds" ([paragraph [0061]). It is deemed obvious to optimize contact time as a result effective variable based upon other known variables such as temperature, composition concentration, expected level of contamination. The

composition is disclosed to be effective against viruses and bacteria. See Abstract. Saud et al. discloses treatment at ambient temperatures. Tu et al. teaches a method of sterilization of hard surfaces using a mixture of an organic ether and an alcohol solvent. Tu et al. further discloses that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to increase and optimize the treatment temperature in Saud et al. to both increase the percent kill and to reduce the treatment time. The determination of the appropriate treatment temperature would have been obviously determinable by the practitioner through routine experimentation. Moreover, as an increase of treatment temperature would have decreased the time necessary to achieve disinfection, the composition of Saud et al. would not have been effective to disinfect a surface at room temperature in the same amount of time as at an elevated temperature.

As to claim 24, Saud et al. evidences that additional antimicrobial agents, such as Triclosan may be added to the formulation. As Saud et al. indicates that attaining regulatory approval may require the addition of additional antimicrobials, it would have been obvious to add Triclosan to the composition. See paragraph [0037].

With respect to claim 28, Saud et al. teaches that the composition is anhydrous and is then diluted with water. See paragraph [0082].

As to claim 43, Saud et al. discloses the importance of complete wetting of the surface with the disinfectant (paragraph [0086]). Given this teaching, the practice of dipping the article in the disinfectant is rendered obvious.

With respect to claim 45, Saud et al. teaches the disinfection of bathroom and kitchen surfaces. It would have been obvious to one of ordinary skill in the art that these surfaces would have included glass, metal, plastic, and ceramics.

As to claim 47, as Saud et al. discloses the disinfection of bathroom and kitchen surfaces, it would have been obvious to employ the method to disinfect a bottle, which are often found in both bathrooms and kitchens.

With respect to claims 51-56 and 59-61, as concentration is a result effective variable, it is deemed obvious to the skilled practitioner to optimize the concentration of the glycol ether by varying the dilution of the composition. Such is readily determinable through routine experimentation.

6. Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saud et al. and Tu et al. as applied to claim 19 above, and further in view of Carter (US 5,686,045).

The combination of Saud et al. with Tu et al. is silent with respect to the use of elevated pressure. Carter discloses that it was known in the art at the time of the invention to use pressure as a means to drive and force an antimicrobial solution into the cracks and crevices of an instrument and also into the outer membrane of a microbe. See Abstract. For this reason, one would have found it obvious to apply an elevated pressure to in the method of Saud et al. with Tu et al..

7. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (US 5,906,802) in view of Waldmann-Laue et al. (US 5,539,001) and Saud et al..

With respect to claim 67, Langford teaches a method of sterilizing a medical instrument

wherein the instrument is first cleaned with a detergent to remove bioburden therefrom, disinfected with a liquid or gas sterilant, rinsed with sterile water, and then dried. See col.1, lines 40-52; col.2, lines 35-42; col.3, lines 16-19; col.5, lines 25-26. Langford does not disclose use of 1-(2-ethylhexyl) glycerol ether as the sterilant. Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using a composition containing an aromatic alcohol and an alkyl glycerol ether having a C_{6-22} alkyl or alkoxymethyl group. The sterilant of Waldmann-Laue et al. is disclosed to be effective at low-temperatures, thereby suggesting that alkyl glycerol ether sterilants would have suitable for the sterilization of the thermolabile medical instruments of Langford. Waldmann-Laue et al. does not disclose that the alkyl glycerol ether is 1-(2-ethylhexyl) glycerol ether, specifically. Saud et al. teaches a method of disinfecting a hard surface employing a composition containing 1-(2-ethylhexyl)glycerol ether. See paragraph [0034]. It would have been obvious to use the ether disclosed by Saud et al. in the combination of Langford with Waldmann-Laue et al., specifically as Saud et al. evidences in paragraph [0034] that 1-(2-ethylhexyl)glycerol ether is a functional equivalent of the alkoxymethyl-containing glycerol ethers disclosed by Waldmann-Laue et al..

As to claim 68 and the limitation directed to "pre-cleaning" (i.e. rinsing) the instrument with water before the initial step of cleaning, Langford discloses that the method employs several cycles of washing, either with or without a detergent, in order to completely remove the bioburden prior to sterilization. See col.1, lines 47-51.

8. Claims 69-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford, Waldmann-Laue et al., and Saud et al. as applied to claim 69 above, and further in view of Tu et al..

With respect to claims 69-74, Langford fails to disclose a treatment temperature. Tu et al. teaches in a method of sterilization that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to optimize the treatment temperature according to the type of instrument being sterilized to both increase the percent kill and to reduce the treatment time.

As to claim 75, Langford fails to teach a treatment time. Tu et al., however, discloses that "[t]he optimum sterilization time is related to the quantity of microorganism present and the level of sterility assurance desired. Consequently, the time can be varied according to needs." See page 8, lines 1-4. In view of the teachings of Tu et al., it would have been obvious to optimize treatment time according to treatment temperature and the quantity of microorganisms present.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 67-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 73-81 of copending Application No. 10/825412. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application and the copending claims differ only in that the copending claims recite "thermal" disinfection. However, as no particular temperature is claimed, the copending claims read on the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed 10 January 2008 have been fully considered but they are not persuasive.

12. On page 13 of the Response, Applicant asserts that the combination of Saud et al. with Tu et al. fails to teach a composition not effective at 25 °C, but effect at about 40 °C to about 80 °C. However, the instant claims (with the exception of claim 67) do not require this. The claims recite only that at 25 °C the composition cannot achieve disinfection in the same period of time

as at 40 °C to about 80 °C. The claims do not preclude the composition from achieving disinfection at room temperature in an extended period of time.

13. On page 14 of the arguments, Applicant alleges that there is no recognition of a composition showing low to no activity at room temperature, but is effective at higher temperatures. Regardless, as discussed in the first [pa]ragraph of the Office Action, the instant specification provides no support for the composition having this activity. Moreover, the specification, if anything, shows that the glycerol ether does indeed have disinfecting action at room temperature.

14. Applicant continues on page 14 with the argument that increasing the temperature in Saud et al. would be discouraged since Saud et al. is an "on the go" composition. The examiner strongly disagrees with this argument as one of ordinary skill in the art would be willing to forego any loss in convenience for a substantial increase in antimicrobial activity. The results of heating a disinfectant solution are shown by Tu et al. to be readily apparent and expected.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leigh McKane/
Primary Examiner, Art Unit 1797

elm
3 March 2008